



UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/089,796	07/24/2002	William J. Bologna	117-389	1022

28765 7590 01/26/2004

WINSTON & STRAWN
PATENT DEPARTMENT
1400 L STREET, N.W.
WASHINGTON, DC 20005-3502

EXAMINER

GEORGE, KONATA M

ART UNIT	PAPER NUMBER
----------	--------------

1616

DATE MAILED: 01/26/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/089,796

Applicant(s)

BOLOGNA ET AL.

Examiner

Konata M. George

Art Unit

1616

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 18 August 2003.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-10, 13-22 and 36-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-10, 13-22 and 36-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
* See the attached detailed Office action for a list of the certified copies not received.
- 13) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.
a) ☐ The translation of the foreign language provisional application has been received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ 6) ☐ Other: _____

DETAILED ACTION

Claims 1-10, 13-22 and 36-38 are pending in this application.

Action Summary

1. Examiner acknowledges the addition of claim 38 in the instant application.
2. Examiner acknowledges the corrections made in the specification as pointed out by examiner.
3. The rejection of claims 1-10, 36 and 37 under the judicially created doctrine of obviousness-type double patenting over claims 1-6 of US Patent No. 6,126,959 is being maintained as stated in the previous office action.
4. The rejection of claims 1-3 and 6-10 under 35 U.S.C. 102(e) as being anticipated by Harrison et al. is hereby withdrawn.
5. The rejection of claims 13-19 and 22 under 35 U.S.C. 102(e) as being anticipated by Harrison et al. as evidenced by Peterson et al. is being maintained for the reasons stated in the previous office action.
6. The rejection of claims 6 and 7 under 35 U.S.C. 102(e) as being anticipated by Peterson et al. is being maintained for the reasons stated in the previous office action.
7. The rejection of claims 4, 5, 20, 21, 36 and 37 under 35 U.S.C. 103(a) over Harrison et al. in view of Peterson et al. is being maintained for the reasons stated in the previous office action.

Claim Rejections - 35 USC § 112

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

8. Claims 13-22 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for the treatment of endometriosis by administering the recited composition, does not reasonably provide enablement for treatment of infertility or improving fertility. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the invention commensurate in scope with these claims.

The claims are drawn to methods for treating endometriosis or infertility, or for improving fertility comprising administering a composition comprising a β -adrenergic agonist (such as terbutaline) and a bioadhesive carrier. Since the prior art teaches the use of β -adrenergic agonist such as terbutaline for treatment of at least pain (dysmenorrhea) associated with endometriosis the claims are enabled for treatment of endometriosis. However, the claims are not enabled for treatment of infertility or improving fertility, as recited alternately, because there is no prior art teaching this effect of the recited composition nor does the instant specification provide any probative evidence that such compositions can treat infertility or improve fertility. This is the paper by E.K. Lang, Amer. J. Roentgenology, vol. 157, 1991, pp 77-80 in which it is shown that terbutaline had some beneficial effects on infertility. However, this was in

conjunction which administration of other medications such as aspirin and there is no clear indication that terbutaline alone would have any beneficial effects on infertility.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1-3, 6-10 and 38 are rejected under 35 U.S.C. 102(e) as being anticipated by Harrison et al (US Pat. No. 6,197,327) as evidenced by Peterson et al. (US Pat. No. 6,207,696 B1).

Harrison discloses a device and method for treatment of dysmenorrhea (i.e. primary or secondary). Column 2, line 20, describe the use of β -adrenergic agonists such as terbutaline in the treatment of dysmenorrhea. One embodiment of the invention further comprises a biocompatible excipient (col. 2, lines 32-36). Examples of excipients include glycerin, mineral oil, polycarbophil, etc. (col. 2, lines 60-63). Column 2, lines 25-31, teach the different types of drug delivery forms such as creams, gels, etc. Example 9, column 15, lines 45-67, describe preparations of compositions comprising different drugs one of which is terbutaline (5mg). The drugs of the composition in example 9 can be substituted for the drugs in examples 4-7. Example 7, lines 5-10,

Art Unit: 1616

teach the use of ibuprofen added to a gel comprising one of several different ingredients one of which is polycarbophil. Therefore, it is the position of the examiner that the use of terbutaline in the composition of example 7 containing polycarbophil is read on the claimed invention. Peterson is relied upon to teach for the showing that secondary dysmenorrhea is the pain associated with endometriosis (col. 4, lines 32-33) (see MPEP 2131.01 for multiple reference 35 U.S.C. 102 rejections). Therefore, a woman having dysmenorrhea resulting from endometriosis would be given the composition of Harrison. The claiming of new use, new function or unknown property which is inherently present in the prior art does not necessarily make the claim patentable, *In re Best*, 562 F.2d 1252, 1254, 195 USPQ 430, 433 (CCPA 1977).

Response to Arguments

10. Applicant's arguments filed August 18, 2003 have been fully considered but they are not persuasive.

Applicant argues that the double patenting rejection is not applicable because the instant invention is directed towards treating endometriosis or infertility using the claimed composition and the composition of the patent treat different conditions. The claim if the instant invention is drawn to a composition, the intended use carries no weight when determining patentability. Both the instant invention and the patent are directed towards compositions containing a therapeutically effective amount of a β -adrenergic agonist together with a pharmaceutically acceptable carrier.

Applicant argues that the examiner has misinterpreted the prior art of Peterson in that Peterson does not teach that dysmenorrhea is associated with endometriosis.

Applicant argues that Peterson in column 4, lines 25-35, merely lists both dysmenorrhea and the pain associated with endometriosis --not endometriosis itself--. Applicant respectfully disagrees. Column 5, lines 10-13 states "The secondary dysmenorrheas that are subject to treatment within the present context have an underlying pathologic origin, such as endometriosis, etc." To the examiner this states that secondary dysmenorrhea can be caused by endometriosis and can be treated using the composition.

Applicant argues that Peterson does not teach using β -adrenergic agonists to treat endometriosis only to treat dysmenorrhea. As previously mentioned Peterson teaches that dysmenorrhea is a pain associated with endometriosis therefore, the composition can be used to treat both dysmenorrhea and endometriosis.

Conclusion

11. Claims 1-10, 13-22 and 36-38 stand rejected.

Telephone Inquiries

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (703) 308-4646. The examiner can normally be reached from 8AM to 5:30PM Monday to Thursday, and on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman Page, can be reached at (703) 308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4556 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-1235.

Konata M. George

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600